K131605

FEB 2 8 2014

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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Date Prepared: May 31, 2013

Device Name

Proprietary name:	(1) Elecsys CMV IgG Immunoassay (2) Elecsys PreciControl CMV IgG
Common name:	(1) CMV IgG (2) PreciControl CMV IgG
Classification name:	(1) Enzyme linked immunoabsorbent assay, cytomegalovirus (2) Single (specified) analyte controls (assayed and unassayed)
Product Code:	(1) LFZ (2) JJX
Predicate Device:	(1) Diamedix Is-CMV IgG (K981163) (2) Elecsys PreciControl Rubella IgG (K072617)

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510(k) Summary, Continued

Device Description

(1) Elecsys CMV IgG is a two-step sandwich immunoassay with streptavidin microparticles, biotinylated recombinant CMV-specific antigen labeled with a ruthenium complex and electrochemiluminescence detection. The results are determined using a calibration curve which is instrument-specifically generated by a 2-point calibration and a master curve provided via the reagent bar code. Results greater than or equal to 1.0 U/mL are considered reactive CMV IgG antibody. The test system contains the human serum-based calibrators intended for use with the system.

(2) Elecsys PreciControl CMV IgG contains liquid control serum based on human serum. The controls are used for monitoring the accuracy of the Elecsys CMV IgG immunoassay.

Note: The reagent and calibrators are packaged together in the Elecsys CMV IgG assay kit, while the associated PreciControl is packaged separately.

Intended Use/Indications for Use

Elecsys CMV IgG:
The Elecsys CMV IgG immunoassay is a test for the in vitro semi-quantitative determination of IgG class antibodies to CMV in human serum, lithium-heparin plasma, K_2 -EDTA plasma, and K_3 -EDTA plasma. The test is intended for adults, including expectant mothers, as an aid in presumptive diagnosis of CMV infection. Results with this assay are used to indicate past infection with CMV.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.

This test is not FDA cleared for screening blood or plasma donors.

The performance of this assay has not been established for use in a pediatric population, neonates and immunocompromised patients or for use at point of care facilities.

Elecsys PreciControl CMV IgG:
Elecsys PreciControl CMV IgG is used for quality control of the Elecsys CMV IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

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Substantial Equivalence	The Elecsys CMV IgG immunoassay test system is substantially equivalent to other devices legally marketed in the United States. (1) Elecsys CMV IgG Immunoassay is equivalent to Is-CMV IgG Test System, Diamedix Corporation (K981163). (2) Elecsys PreciControl CMV IgG is equivalent to the Elecsys PreciControl Rubella IgG (K072617).
Substantial Equivalence - Comparison	The following tables compare the Elecsys CMV IgG immunoassay and PreciControl CMV IgG with their respective predicate devices.

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Comparison of Assays—Similarities and Differences

Immunoassay Comparison		
Feature	**Elecsys HSV-2 IgG Reagent and Calibrator (Candidate Device)**	**Is-CMV IgG Test System (Predicate Device: K981163)**
General Assay Features		
Intended Use/ Indications for Use	The Elecsys CMV IgG immunoassay is a test for the in vitro semi-quantitative determination of IgG class antibodies to CMV in human serum, lithium-heparin plasma, K_2 -EDTA plasma, and K_3 -EDTA plasma. The test is intended for adults, including expectant mothers, as an aid in presumptive diagnosis of CMV infection. Results with this assay are used to indicate past infection with CMV.	For the qualitative and semi-quantitative detection of IgG antibodies to cytomegalovirus (CMV) in human serum by indirect enzyme immunoassay to aid in the assessment of the patient's immunological response to CMV and to determine the immune status of individuals, including females of child-bearing age. The evaluation of acute and convalescent sera can aid in the diagnosis of primary infection, reactivated infection or reinfection with CMV. This product is not FDA cleared for use in screening blood and plasma donors.
Assay Protocol	Sandwich assay	Solid phase microtiter
Detection Protocol	Electrochemiluminescent Immunoassay	Enzyme-linked immunosorbent assay
Applications	18 minutes	N/A

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Comparison of Assays—Similarities and Differences

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
General Assay Features		
Instrument Platform	Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 411, **cobas e** 601, and **cobas e** 602	Automated EIA Processor or Manual
Sample Volume	20 µL	100 µL after dilution
Sample Type	Human serum and Lithium-heparin, K_2-EDTA, and K_3-EDTA plasma	Human whole blood and serum
Reagents	Reagents consist of streptavidin-coated microparticles, biotinylated CMV antigen (recombinant, from *E. coli*), ruthenylated CMV antigen (recombinant, from *E. coli*), and negative and positive calibrators.	Reagents consist of partially purified CMV antigen (AD-169 strain produced in human fibroblasts) coating the antigen wells.
Calibrator	Included with the reagent kit	Included in the reagent kit as Diamedix CMV IgG Standards
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: • After 27 days when using the same reagent lot. • After 7 days when using the same reagent kit on the analyzer. • As required: e.g. quality control findings with PreciControl CMV IgG outside the defined limits.	Calibration, using Diamedix CMV IgG Standards, occurs with each use of the antigen wells.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
General Assay Features		
Controls	Elecsys PreciControl CMV IgG	High positive, low positive, and negative controls included in the reagent kit
Traceability / Standardization	The Elecsys CMV IgG assay has been standardized against the Roche internal standard for CMV IgG. No international standard is available for CMV.	The Diamedix CMV IgG "Standards" (calibrators) are traceable to in-house reference materials and not to any recognized national or international standard preparation.
Reagent Stability	**Reagents (ready to use):** • 2-8°C – Up to the stated expiration date • After opening at 2-8°C – 12 weeks • On the analyzers – 4 weeks **Calibrators (ready to use):** • Unopened at 2-8°C – Up to stated expiration date • After opening at 2-8°C – 8 weeks • On the Elecsys 2010 and **cobas e** 411 20-25°C – Up to 5 hours • On the MODULAR ANALYTICS E170, **cobas e** 601, and **cobas e** 602 – Use only once	Kits and reagents are stable through their expiration dates when stored at 2-8°C.
Results	The analyzer automatically calculates the analyte concentration of each sample in U/mL.	Positive, equivocal, or negative results are generated by this assay automatically when utilizing the Automated EIA Processor.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
General assay features		
Result Interpretation	Results obtained with the Elecyss CMV IgG assay can be interpreted as follows: • Non-reactive: < 0.5 U/mL • Indeterminate: 0.5 - < 1.0 U/mL • Reactive: ≥ 1.0 U/mL	Results of this test are negative, equivocal, or positive for anti-CMV IgG, as defined below: • Negative - <8.0 EU/mL, Index < 0.80 • Equivocal – 8.0 to 9.9 EU/mL, Index 0.8 to 0.99 • Positive - ≥ 10.0 EU/mL, Index ≥ 1.0
Limits of Measurement	LoB = 0.15 U/mL LoD = 0.25 U/mL	Not applicable
Hook Effect	No hook effect up to 2500 U/mL	Not tested

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
Labeled Performance Characteristics		
Precision	Elecsys 2010 and **cobas e** 411 *Intra-assay/Repeatability:* • Negative Control: SD 0.004 U/mL • Low Control: CV 0.9 – 1.6% • High Control: CV 0.7 – 1.4% • Serum Samples < 1.0 U/mL: CV 1.5 – 1.9% • Serum Samples ≥ 1.0 U/mL: CV 1.2 – 1.5% *Intermediate Precision:* • Negative Control: SD 0.005 U/mL • Low Control: CV 3.2 – 3.3% • High Control: CV 3.1 – 3.3% • Serum Samples < 1.0 U/mL: CV 3.2 – 3.4% • Serum Samples ≥ 1.0 U/mL: CV 2.6 – 3.9% E170, **cobas e** 601, and **cobas e** 602 *Intra-assay/Repeatability:* • Negative Control: SD 0.003 U/mL • Low Control: CV 1.0 – 2.0% • High Control: CV 1.1 – 1.6% • Serum Samples < 1.0 U/mL: CV 1.7% • Serum Samples ≥ 1.0 U/mL: CV 1.2 – 2.0%	Manual Preparation *Intra-assay/Repeatability:* • Negative Control: SD 0.12 – 0.31 EU/mL • Low Control: CV 5.23 – 10.78% • High Control: CV 2.46 – 12.07% • Serum Samples < 10.0 EU/mL: SD 0.26 – 2.12 EU/mL • Serum Samples ≥ 10.0 EU/mL: CV 1.03 – 13.90% *Intermediate Precision:* • Negative Control: SD 0.25 – 0.45 EU/mL • Low Control: CV 7.10 – 8.76% • High Control: CV 3.41 – 11.00% • Serum Samples < 10.0 EU/mL: SD 0.31 – 2.44 EU/mL • Serum Samples ≥ 10.0 EU/mL: CV 4.37 – 21.33% Automated Preparation *Intra-assay/Repeatability:* • Negative Control: SD 0.70 EU/mL • Low Control: CV 5.05% • High Control: CV 8.38% • Serum Samples < 10.0 EU/mL: SD 0.43 – 0.56 EU/mL • Serum Samples ≥ 10.0 EU/mL: CV 5.39 – 18.07%

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
Labeled Performance Characteristics		
Precision (continued)	*Intermediate Precision:* • Negative Control: SD 0.004 U/mL • Low Control: CV 3.2 – 4.2% • High Control: CV 3.7 – 4.2% • Serum Samples < 1.0 U/mL: CV 4.0% • Serum Samples ≥ 1.0 U/mL: CV 3.2 – 4.5%	*Intermediate Precision:* • Negative Control: SD 0.71 EU/mL • Low Control: CV 8.77% • High Control: CV 6.68% • Serum Samples < 10.0 EU/mL: SD 0.54 – 0.74 EU/mL • Serum Samples ≥ 10.0 EU/mL: CV 9.43 – 15.46%
Cross-Reactivity	249 samples, which were positive for the following cross reactants, were tested with the Elecsys CMV IgG and the predicate device: Autoimmune, EBV, E.Coli, HAV, HBV, HCV, HIV, HSV, HTLV, influenza vaccine, rubella, syphilis, and toxoplasmosis. 98.9% agreement was demonstrated between the two assays.	The sponsor tested 47 CMV IgG-negative samples which were positive for at least one of the followingcross reactants: VZV IgG, HSV, toxoplasmosis, rubella, EBV, and measles. No cross-reactivity was observed.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
Labeled Performance Characteristics		
Limitations	• A negative test result does not completely rule out the possibility of an infection with CMV. Individuals may not exhibit any detectable IgG antibodies at the early stage of acute infection. • The detection of CMV-specific IgG antibodies in a single sample indicates a previous exposure to CMV but is not always sufficient to distinguish between an acute or latent infection (irrespective of the level of the IgG antibody titer). • In rare cases of primary CMV infection IgG antibody may be present before a specific IgM antibody response is detected. It is recommended that a follow-up sample be tested after 2 weeks. If the CMV IgG antibody titer remains stable, a primary infection can be excluded. • Elecsys CMV IgG results should be used in conjunction with the patient's medical history, clinical symptoms and other laboratory tests, e.g. CMV-specific IgM results, CMV IgG avidity results.	• The results obtained with the *Is*-CMV IgG Test Kit serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. • Assay performance characteristics have not been established for visual result determination. • The test should be performed on serum. The use of whole blood or plasma has not been established. • The presence of IgG antibodies in a single serum sample is not sufficient to distinguish between active and past infection. A test for IgM antibodies may be performed for patients suspected of primary infection with CMV. • Performance of this assay has not been established on spectrophotometry utilizing a single wavelength. • The performance characteristics have not been established for prenatal populations or newborns. • The results on serum from immunosuppressed individuals must be interpreted with caution.

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510(k) Summary, Continued

Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
Labeled Performance Characteristics		
Limitations, continued	• The results in HIV patients, in patients undergoing immunosuppressive therapy, or in patients with other disorders leading to immune suppression, should be interpreted with caution. • Specimens from neonates, cord blood, pretransplant patients or body fluids other than serum and plasma, such as urine, saliva or amniotic fluid, have not been tested. • There is no high-dose hook effect at CMV IgG concentrations up to 2500 U/mL. • The assay is unaffected by icterus (bilirubin < 1129 µmol/L or < 66 mg/dL), hemolysis (Hb < 1000 mg/dL), lipemia (Intralipid < 2000 mg/dL), biotin (< 100 ng/mL) and human serum albumin (< 20 g/dL). Criterion: Mean recovery of positive samples within ± 20 % of serum value. • Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration. • No interference was observed from rheumatoid factors up to a concentration of 1600 IU/mL.	• Studies demonstrating the effectiveness or monitoring of antiviral treatments have not been performed. • Definitive diagnosis of active CMV infection requires viral isolation. The presence of IgG antibody to CMV does not ensure protection from the disease. • The performance characteristics of the Diamedix *Is*-CMV IgG Test Kit with automated equipment other than the MAGO® Plus Automated EIA Processor have not been established.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
Labeled Performance Characteristics		
Limitations, continued	• In vitro tests were performed on 18 commonly used pharmaceuticals and in addition on ganciclovir and valganciclovir. No interference with the assay was found. • In rare cases, interference due to extremely high titers of antibodies to immunological components, streptavidin or ruthenium can occur. These effects are minimized by suitable test design. • For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	

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510(k) Summary, Continued

Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys CMV IgG Reagent and Calibrator (Candidate Device)**	**Diamedix Is-CMV IgG (Predicate Device: K981163)**
Labeled Performance Characteristics		
Percent Agreement/ Relative Sensitivities and Specificities	***Routine Cohort (n=500)*** Positive Percent Agreement (95% CI): 100% (98.7-100%) Negative Percent Agreement (95% CI): 90.1% (85.3-93.7%) ***Expectant Mother Cohort (n=98)*** Positive Percent Agreement (95% CI): 100% (95.4-100%) Negative Percent Agreement (95% CI): 73.7% (48.8-90.9%) ***CMV IgM Positive Cohort (n=119)*** Positive Percent Agreement (95% CI): 96.6% (91.6-99.1%) Negative Percent Agreement (95% CI): 100% (2.5-100%)	***Relative Sensitivities to EIA*** Manual (95%CI) Site 1 (n=195): 99.3% (96.3-100.0%) Site 2 (n=168): 96.6% (91.5-99.1%) Site 3 (n=205): 100.0% (97.6-100.0%) ***Relative Sensitivities to EIA*** Automated (95% CI) Site 3 (n=201): 100.0% (97.6-100.0%) **Relative Specificities to EIA** Manual (95% CI) Site 1 (n=195): 97.9% (88.9-99.9%) Site 2 (n=168): 100.0% (93.0-100.0%) Site 3 (n=205): 94.3% (84.3-98.8%) **Relative Specificities to EIA** Automated (95% CI) Site 3 (n=201): 87.7% (75.2-95.4%)

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Comparison of Controls – Similarities and Differences

Characteristic	Elecsys PreciControl CMV IgG (Candidate Device)	Predicate Device: Elecsys PreciControl Rubella IgG (K072617)
Intended Use	PreciControl CMV IgG is used for the quality control of the Elecsys CMV IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys PreciControl Rubella IgG is used for quality control of the Elecsys Rubella IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Three	Two
Format	Liquid, ready for use	Liquid, ready for use
Matrix	Human serum	Human serum
Analyte Concentration	PreciControl 0: <0.25 U/mL PreciControl 1: ~1.5 U/mL PreciControl 2: ~25 U/mL	PreciControl 1: ~4.0 IU/mL PreciControl 2: ~75 IU/mL
Stability	Unopened: • Store at 2-8°C up to the stated expiration date Opened: • 2 - 8°C: 8 weeks • On the Elecsys 2010 and **cobas e** 411 analyzers at 25°C: Up to 5 hours • On the MODULAR ANALYTICS E170, **cobas e** 601, and **cobas e** 602 analyzers 25°C: Up to 2 hours	Unopened: • Store at 2-8°C up to the stated expiration date Opened: • 2 - 8°C: 8 weeks • On the analyzer at 20-25°C: Up to 5 hours
Handling	The controls are supplied ready-for-use in bottles compatible with the system. When measuring non-Roche controls, use only recommended sample tubes, cup on tube or cup on rack. Elecsys 2010 and **cobas e** 411 analyzers: The original control vials may be used if the entire provided volume is used and no aliquots are prepared. The controls should only be lef t on the analyzer during performance of quality control. After use, close the bottles as soon as possible ans store upright at 2-8°C. Due to possible evaporation effects, not more than 7 quality control procedures per bottle should be performed.	The controls are supplied ready-for-use in bottles compatible with the system. The controls should only be left on the analyzer during performance of quality control. After use, close the bottles as soon as possible and store upright at 2-8°C. Because of possible evaporation effects, not more than 7 quality control procedures per bottle should be performed.

510(k) Summary, Continued

Evaluations Summary

(1) The Elecsys CMV IgG Immunoassay was evaluated for several performance characteristics, including precision, LoB and LoD, high dose hook effect, cross reactivity, method comparison between analyzer platforms, interfering substances, and reagent, calibration, and sample stability.

(2) The Elecsys PreciControl HSV was evaluated for value assignment and stability.

A summary of the evaluation studies is provided in Section IV.

Additionally, the Elecsy CMV IgG assay was evaluated in a clinical trial using an adult cohort that included specimens from pregnant subjects and CMV IgM-positive subjects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ROCHE DIAGNOSTICS
JANE PHILIPS, Ph.D.
REGULATORY AFFAIRS PROGRAM MANAGER
9115 HAGUE ROAD
INDIANAPOLIS IN, 46250

February 28, 2014

Re: K131605
Trade/Device Name: Elecsys CMV IgG Assay and Elecsys PreciControl CMV IgG
Regulation Number: 21 CFR 866.3175
Regulation Name: Cytomegalovirus serological reagents
Regulatory Class: II
Product Code: LFZ, JJX
Dated: January 28, 2014
Received: January 29, 2014

Dear Dr. Philips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Sally A. Hojvat, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131605

Device Name: Elecsys CMV IgG Assay

Indications for Use:

The Elecsys CMV IgG assay is an in vitro qualitative test for the detection of IgG antibodies to CMV in human serum, lithium-heparin plasma, K_2-EDTA plasma, and K_3-EDTA plasma. The test is intended as an aid in the determination of the serological status to CMV in individuals in which a CMV IgG test was ordered, including pregnant women.

Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. This test is not intended for use in neonatal screening or for use at point of care facilities. This test is not intended for use in screening blood and plasma donors. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Device Name: Elecsys PreciControl CMV IgG

Indications for Use:

Elecsys PreciControl CMV IgG is used for quality control of the Elecsys CMV IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Stephen J. Lovell -S
2014.02.28 10:00:25 -05'00'